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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,088

12/06/2004

Jianming Chen

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,088	Applicant(s) CHEN ET AL.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in the prosecution are 7-12.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicants intend to convey by 'serving as accessories' in claim 1. A buffer is an aqueous solution and it is therefore, it is unclear as to what the expression 'buffer and water' is intended to convey.

'one or several sorts of materials' and 'etc'. render claim 8 indefinite. The examiner suggests 'support substance is selected from the group consisting of ----- and mixtures thereof and delete, 'etc.'. Similar is the case with claim 9.

'according to your needs' renders claim 10 indefinite since it is unclear as to what the needs are.

The examiner suggests reciting specific steps in claim 12 and avoid expressions\ such as 'can also be obtained from the lipid solution'. A method claim should recite specific method steps.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al US 2003/0118616 in view of West et al (4,781,871).

Lee et al disclose liposomal formulations containing lecithin, 0011, 0023, Retinol (Vitamin A), 1 % and sorbitol (2 %) (abstract and Table 4 on page 5). What is lacking in Lee et al is the teaching of the use of mannitol.

West et al while disclosing liposomal compositions containing active agents teach the equivalency between sorbitol and mannitol, (abstract and col. 15, line 65 through col. 16, line 1).

The use of mannitol instead of sorbitol in the liposomes of Lee et al with a reasonable expectation of success would have been obvious to one of ordinary skill in the art since West et al teach the equivalency between sorbitol and mannitol.

5. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller (6,610,322) by itself or in view of Clerc (5,939,096).

Keller discloses liposomal preparations containing tretinoin (Example 7). Keller

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further suggests that the liposomes can be lyophilized in the presence of appropriate cryoprotectant (col. 7, lines 30-35). Although Keller does not disclose mannitol as the cryoprotectant and its amounts, it would have been obvious to use mannitol in appropriate amounts since mannitol is a known cryoprotectant and it minimizes liposomal damage during freezing and rehydration (col. 8, lines 9-15) as also evident from Clerc. The use of lecithin would have been obvious to one of ordinary skill in the art since Clerc also shows that it is commonly used phospholipid in liposomal preparations (col. 8, lines 58-62).

6. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Cole (6,544,531) or Meybeck (5,034,228) in view of Clerc (5,939,096).

Cole discloses liposomes containing retinol. The compositions also contain Brij (Example 1).

Meybeck similarly discloses liposomal compositions containing tretinoin. Meybeck further teaches lyophilizing the composition (Examples 3-7).

What are lacking in Cole and Meybeck are the teachings of the inclusion of mannitol. Cole further lacks lyophilization of the composition.

Clerc as discussed above, teaches that the liposomes can be stored in a lyophilized form and that mannitol acts as a cryopreservative and minimizes the liposome damage during freezing and thawing.

It would have been obvious to use mannitol in appropriate amounts in the compositions of Cole or Meybeck since mannitol is a known cryoprotectant and it minimizes liposomal damage during freezing and rehydration as shown by Clerc.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

GSK